

### **REMARKS**

Claim 13 has been amended to recite "for topical administration to human skin." Support for the amendment is found in the specification at, for example, page 16, lines 17-25 and page 25, lines 14-16. Claim 13 has also been amended to recite "a cosmetic auxiliary agent." Support for the amendment is found in the specification at, for example, page 16, lines 24-28 and page 20, line 1 to page 25, line 13. (The citations to the specification refer to the published International application, WO2005/053631.)

No new matter has been added by any of the amendments.

### ***Anticipation Rejection***

Claims 13 and 26-32 were rejected under 35 U.S.C. § 102(b) as being anticipated by Spange et al., *Angew. Chem. Int. Ed.* (2002) 41, p. 1729-1732 ("Spange"). (Paper No. 20100806 at 2.)

Spange discloses a one-pot synthesis of chromophoric silicate-based xerogels using a sol gel process. (Title; Page 1729, left column, first full paragraph.) Spange also discloses use of xerogels in applications such as "nonlinear-optical (NLO) materials, semiconductors, or for use in sensors." (Page 1729, lines 7-8.)

In making the rejection with respect to claim 13, the Examiner asserted that "Spange et al. discloses a chromophoric silicate-based xerogel wherein the encapsulated components show improved retention within the microcapsule due to a new sol-gel procedure (pg. 1729, left column, second paragraph). The first step of the

encapsulation procedure involves the covalent modification of a trialkoxysilane with an organic (e.g. chromophoric) group (reads on the crosslinkable chromophore monomer of the instant invention) (pg. 1729, left column, second paragraph). More specifically, a fluorine atom in a chromophoric substance such as fluorobenzophenone, a UV-A absorber (reads on the UV-A filter activity of the crosslinkable monomer of the instant invention) (pg. 1729, right column, first paragraph; Table 1) is substituted by a primary or secondary amine bonded to an alkoxy silane in tetraethoxysilane (TEOS) (e.g. aminopropyltrimethoxysilane, APS). The functionalized trialkoxysilane is subsequently converted into an organically modified silica gel (i.e. sol-gel hybrid; page 1729, Scheme 1) by addition of tetraalkoxysilane (reads on the crosslinkable monomer of the instant invention) in the absence of a non-crosslinkable chromophore (pg. 1729, left column, third paragraph). (Id. at 2-3.)

The Examiner acknowledged that "Spange does not refer to its silicate-based xerogel as a sunscreen composition," however, the Examiner asserted that "due to the elements and nature of xerogel composition, the xerogel composition of Spange would be expected to [possess] the same sunscreensing abilities as that of the instant invention." (Id. at 3.)

The Examiner also asserted:

Regarding claim 26, Spange et al. discloses a sol-gel chromophore hybrid containing a chromophore with UV-A and/or UV-B filter activity such as fluorobenzophenone (page 1729, right column, first paragraph). The spacer group  $(B)_b(C)_c(D)_d(E)_e$  is optional because b, c, d, and e could be 0 or 1.

Regarding claims 27, 28, Spange et al. discloses a sol-gel process resulting in a sol-gel hybrid material (equivalent of the crosslinkable chromophore with

UV filter activity) (Scheme 1 : page 1729, right column) is a crosslinkable monomer prepared by reacting a UV-A, UV-B, and/or UV-C chromophore such as a fluorinated benzophenone (equivalent of "P" of the general formula  $M(R)_n(P)_m(Q)_q$  of the instant invention) with a aminoalkylalkoxysilane (APS) to give rise to a chromophoric xerogel such as 4-fluorobenzophenone:aminopropyltrimethoxysilane (APS) (equivalent of the chromophore monomer of Ex. 1 : (triethoxysilyl)propyloxyphenylbenzoxazole, and equivalent of the  $M(R)_n(P)_m(Q)_q$  where M is a silicon element, R is [a hydrolyzable] group such as an alkoxides [sic] and Q is a non-hydrolyzable group such as [a]  $C_1-C_6$  alkyl group as cited in paragraph 18-26 of the specification) (page 1730, Table I; page 1730, right column, first paragraph).

Regarding claim 29, Spange et al. discloses a sol-gel chromophore hybrid containing a silane with at least two  $C_{1-6}$  alkoxy groups (fluorobenzophenone:aminopropyltrimethoxysilane) (page 1730, Table 1).

Regarding claim 30, Spange et al. discloses using a crosslinkable silane monomer in the process of sol-gel chromophore hybrid production, wherein the silane monomer is tetraethoxysilane (reads on at least two  $C_{1-6}$  alkoxy groups of the instant claim) (page 1729, left column, third paragraph).

Regarding claim 31, Spange et al. discloses that when chromophoric substances such as 4-nitroaniline derivatives are incorporated into the silicate matrix, uniformly spherical particles with a narrow size-distribution of less than  $2\mu m$  in diameter are formed (page 1729, right column, second paragraph; page 1731 : figure 2).

Regarding claim 32, Spange discloses that the sol-gel materials prepared using this method contains up to 20% organofunctionalized silane (chromophoric silane) (pg. 1729, right column, second paragraph). [Id. at 3-4.]

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346

(CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.* 221 USPQ 481, 485 (Fed. Cir 1984).

To forward prosecution in the present application, claim 13 has been amended to recite “[a] sunscreen composition *for topical administration to human skin* comprising microcapsules having UV filter activity ... *and a cosmetic auxiliary agent.*”

Spange does not disclose sunscreen compositions. As the Examiner has acknowledged, “Spange does not disclose sunscreen compositions.” (Paper No. 20100806 at 3; see also *id.* at 7.) Spange discloses, rather, preparation of xerogels for use in applications such as “nonlinear-optical (NLO) materials, semiconductors, or for use in sensors.” (Page 1729, lines 7-8.) Accordingly, one skilled in the art would understand that Spange neither formulates the disclosed xerogels “for topical administration to human skin” nor with “a cosmetic auxiliary agent,” as recited in amended claim 13.

Because the sol gel materials of Spange lack inclusion of a cosmetic auxiliary agent, Spange does not disclose each and every element of the claimed invention. For this reason alone, the rejection should be withdrawn.

Furthermore, the xerogel produced according to the one-pot synthesis of Spange is not suitable for formulation in a cosmetic formulation, i.e., for topical administration to human skin. Spange discloses that the sol gel hybrid materials are synthesized in tetraethoxysilane (“TEOS”) as the solvent. (Page 1729, left column, line 22-26 and right column, lines 1-3.) Material Safety Data Sheets which are attached as Exhibit A indicate that TEOS is a hazardous substance. One skilled in the art would know that the xerogel compositions of Spange cannot be used as cosmetic sunscreen

compositions because TEOS is toxic. As is known to the skilled person, it is necessary that a "sunscreen composition" for topical use as recited in e.g., claim 13, have acceptable skin tolerance and be able to spread well onto the skin. In particular, in sunscreen compositions only skin-tolerable and nontoxic substances are permissible. These characteristics of cosmetic formulations are not met by Spange in view of the disclosed uses such as "non-linear optical (NLO) materials, semiconductors, or for use in sensors". (Col. 1, lines 7-8.) The compositions of Spange are far from "sunscreen compositions" for topical administration to human skin. Thus, for this reason as well the rejection is insufficient.

In view of all of the foregoing, it is submitted that each and every element of the amended claims is not present in Spange. Accordingly, the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

### ***Obviousness Rejections***

#### **A. Rejection over Avnir**

Claims 13 and 26-31 were rejected under 35 U.S.C. § 103(a) as being obvious over Avnir et al., U.S. Patent No. 6,159,453 ("Avnir"). (Paper No. 20100806 at 5.)

Avnir discloses "sunscreen-doped sol-gel materials useful for protecting body tissues, such as skin, nails and hair and other surfaces from sunlight radiation. The sol-gel matrices are transparent to the UV radiation in the range above 250 nm and the doped sunscreen agents are either chemical or physical sunscreens capable of absorbing the UV radiation in the range above 250 nm." (Abstract, lines 1-7.) Avnir

also discloses "a method for the preparation of sunscreen-doped sol-gel materials comprising condensation-polymerizing of at least one monomer ... in the presence of at least one sunscreen ingredient, resulting in the entrapment of the sunscreen ingredients within the formed sol-gel matrix." (Abstract, lines 12-23.) Avnir further discloses that "[t]he preparation of sunscreen-doped sol gel matrices is simple; direct physical entrapment in the course of sol-gel polymerization is possible and no reaction with the sunscreen molecule itself is needed." (Col. 4, lines 31-34.) Thus, sunscreen molecules that are added to the polymerizing mixture, either prior to or after hydrolysis of the monomer, are entrapped within the sol-gel matrix but not covalently bonded to the matrix. (Col. 4, lines 31-34; Col. 3, lines 33-51.)

In making the rejection, the Examiner asserted with regard to claims 13 and 26 that "Avnir et al. discloses a method of preparing a sol-gel material with trapped sunscreen comprising condensation-polymerization of at least one monomer selected [from] metal alkoxides and from monomers of the formula  $M(R)_n(P)_m$ , wherein M is a metallic or semi metallic element (such as silicon, titanium, zinc, aluminum, zirconium) R is a hydrolyzable substituent (such as alkoxides, aryloxides, carboxylic esters, acyloxy groups, diketonato groups, [hydrolyzable] aza groups and chlorine), n is an integer from 2 to 6, P is a non polymerizable substituent (reads on the crosslinkable monomer of the instant invention) or a sunscreensing moiety or derivative (reads on the crosslinkable chromophore monomer of the instant invention) and m is an integer from 0 to 6, in the presence of at least one sunscreen ingredient, resulting in the entrapment of the sunscreen ingredients within the formed sol-gel matrix (col. 3, lines 33-46)." (Paper No. 20100806 at 5.)

The Examiner also asserted:

Regarding claims 27, 28, 30, Avnir teaches using a combination of tri- and tetraalkoxysilane monomers (col. 4, lines 48-51; col. 5, lines 44-48) in the presence of basic or acidic catalysts for entrapping sunscreen agents such as cinnamate, salicylate, and benzophenone (col. 6, lines 8-27), as well as surfactants (col. 5, lines 51-67).

Regarding claim 29, Avnir et al. teaches chromophoric monomers of the formula  $M(R)_n(P)_m$ , with R being a [hydrolyzable] group such as an alkoxides group [sic] and n is an integer from 2-6 (col. 3, lines 33-46) (reads on at least two  $C_{1-6}$  alkoxy groups of the instant claim).

Regarding claim 31, Avnir et al. discloses the sol-gel matrices are particles in the range of 0.01 -100 microns in diameter (col. 3, lines 8-31). [Id. at 5-6.]

The Examiner also asserted that “[although] Avnir’s sunscreen composition contains non-crosslinkable chromophores in addition to crosslinkable chromophores, it is the examiner’s position that one of ordinary skill in the art would find [sic] it obvious not to include the extra sunscreensing component to the sol-gel composition as long as a satisfactory sunscreensing effect is achieved with the crosslinkable chromophores alone.” (Id. at 6.)

The Examiner further asserted that “Avnir teaches that its sol-gel sunscreen material comprises two components: one is a metal alkoxide monomer of formula  $M(R)_n(P)_m$  which contains a sunscreensing moiety ‘P’, and a noncrosslinked sunscreen monomer. It would be obvious [sic] to one skilled in the art to leave out the non-crosslinkable sunscreen moiety as long as there is a sunscreen component present in the sol-gel matrix in order to reduce the chances of getting free sunscreen monomers in contact with skin and thus improve the safety of the sunscreen composition.” (Id.)

Furthermore, the Examiner asserted that “[t]he prior art has recognized the problem with absorption of chromophore monomers in sunscreen products and has proposed and invented a sunscreen product that isolated chemical sunscreens from the body and reduced the chances of the skin coming in contact with free chromophore (col. 1, lines 55-66). Along the same line of reasoning, it would be obvious [sic] not to include a non-crosslinkable chromophore in the sunscreen component if there is enough of the crosslinkable chromophore attached to the metal alkoxide monomer.” (Id. at 6-7.)

The Examiner further asserted that “the applicant is taking a step backward to omit part of a sunscreen which is not desired to possibly make it more cost efficient or to make it more leach proof.” (Id. at 7.)

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness “**analysis should be made explicit**” and the teaching-suggestion-motivation test is “**a helpful insight**” for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60



USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test “***must be based on objective evidence of record.***” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). See also *Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) (“The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.”).

Here, what the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosure of Avnir in the manner proposed by the Examiner to arrive at the claimed material obtained from a heterophase composition. As is well settled, an Examiner cannot establish obviousness by locating document(s) which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that “it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound”) (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

With a view toward forwarding prosecution in the present application, claim 13 has been amended as indicated above.

As noted above, Avnir discloses that the sol-gel matrix is transparent to the UV range above 250 nm. The transparency permits UV-A and UV-B light to penetrate the sol-gel particles and interact with the entrapped sunscreen molecules. One skilled in the art would understand that an essential part of Avnir is that non-crosslinked chromophores are present in the sol-gel matrix. Indeed, Avnir particularly touts the advantage of entrapping the chromophores without crosslinking, as this way "no reaction with the sunscreen molecule itself is needed". (Col. 4, lines 23-33). One skilled in the art reading Avnir would recognize that Avnir's sunscreen could only provide sufficient UV protection when non-crosslinked chromophores are entrapped in the transparent sol-gel matrix. Thus, Avnir considers the free monomeric sunscreen molecules to be essential in order to obtain suitable sunscreen protection.

With regard to the claimed invention, however, it has been found that contrary to the disclosure of Avnir it is not necessary to dope particles of a sol-gel matrix with monomeric sunscreen molecules.

One skilled in the art would not reasonably expect, in view of Avnir, that microcapsules prepared by the sol-gel method which are free of monomeric sunscreen molecules, would provide a sufficiently high SPF value to be useful in cosmetic sunscreen agents. No examples of sunscreen compositions as presently claimed are disclosed in Avnir, and no process for preparing a sol-gel matrix according to the present application is provided. Avnir does not suggest or consider that a sunscreen moiety covalently bonded to the matrix of the sol-gel particles in the absence of non-crosslinkable chromophores with UV-A and/or UV-B and/or UV-C filter activity would be sufficient to provide a reasonable sun-protecting factor in a cosmetic composition. Far

from suggesting the present invention, Avnir leads one skilled in the art away from the claimed invention because Avnir considers it as essential that the sol-gel matrix have entrapped sunscreen molecules to provide a sufficient sun-protecting factor for use in cosmetic compositions.

Avnir recognizes that that chemical sunscreens may be carcinogenic (Col. 1, line 66 to Col. 2, line 1) and the "great need for isolating chemical ... sunscreen agents from the body while retaining ... the sunscreen activity...." (Col. 1, line 65 to col. 2, line 5). In connection with Avnir's disclosed sunscreen-doped sol-gel materials, Avnir discloses that "[t]he entrapped sunscreen molecules are not in direct contact with the skin." (Col. 4, lines 53-55.) Yet Avnir does not disclose, suggest, or provide motivation to solve the problem of monomeric sunscreen agents coming into contact with the skin and to provide an effective sunscreen in any way other than Avnir's transparent sol gel material doped with monomeric sunscreen agents.

The Examiner has mischaracterized the use of non-crosslinkable chromophores of Avnir as "extra". The Examiner stated that "it is the examiner's position that one of ordinary skill in the art would find [sic] it obvious not to include the extra sunscreens component to the sol-gel composition as long as a satisfactory sunscreens effect is achieved with the crosslinkable chromophores alone." (Paper No. 20100806 at 6.) The disclosure of Avnir indicates that non-crosslinkable chromophores are essential, as indicated above, rather than "extra," as improperly characterized by the Examiner.

Furthermore, Avnir contains no suggestion or motivation to achieve the claimed sunscreen composition having crosslinkable chromophores as recited and

which is “free from non-crosslinkable chromophores with UV-A and/or UV-B and/or UV/C filter activity.” Nor does Avnir contain any indication or suggestion that use of “crosslinkable chromophores alone,” as referred to by the Examiner, could possibly achieve “a satisfactory sunscreensing effect”; nor does Avnir suggest how one would go about achieving such hypothetical effect.

As indicated previously on the record, the Court of Appeals for the Federal Circuit has reaffirmed that “hindsight claims of obviousness” are improper. In distinguishing between fact patterns where a combination of known elements may or may not be proper, the Federal Circuit clearly articulated that simply varying all possible parameters until the claimed invention is arrived at in the absence of either an indication of which parameters to vary or an indication of which of many possible choices is likely to be successful is impermissible hindsight reconstruction. Indeed, the Federal Circuit concluded:

Similarly, patents are not barred just because it was obvious “to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 90 USPQ2d 1947, 1951 (Fed. Cir. 2009), citing *In re O’Farrell*, 853 F.2d at 903.

In addition, to achieve the claimed sunscreen composition which comprises “microcapsules having UV filter activity made by a sol-gel method and which are free from non-crosslinkable chromophores with UV-A and/or UV/B and/or UV/C filter activity,” the Avnir composition would have to be altered in a manner not intended and, in fact, contrary to its teaching. As is well settled, to do what the prior art teaches against is the very antithesis of obviousness. See, e.g., *In re Rosenberger*, 156 USPQ

24, 26 (CCPA 1968) and *In re Buehler*, 185 USPQ 781, 787 (CCPA 1975). For this reason alone, the rejection should be withdrawn.

Furthermore, it is respectfully submitted that the Examiner has not applied the correct law due to an erroneous characterization of the facts. In asserting that “the applicant is taking a step backward to omit part of a sunscreen which is not desired to possibly make it more cost efficient or to make it more leach proof,” the Examiner also stated that “[e]limination of an element and its function is obvious if the function of the element is not desired,” *citing* MPEP 2144.14II[A] and *Ex parte Wu*, 10 USPQ 2031 (BPAI 1989). Instead of being a situation in which there is a determination of obviousness where there is omission of an element and its function where the function of the element is not desired (MPEP 2144.04IIA; *Ex part Wu*, 10 USPQ 2031 (BPAI 1989)), the claimed invention may properly be characterized as omission of an element with retention of the element’s function. The aspect of an omission, i.e., recited lack in the claim language of non-crosslinkable chromophores in the claimed sunscreen composition, yet retention of function, i.e., sunscreen activity in the presence of a crosslinkable chromophore as recited, are indicia of ***unobviousness***, according to the Manual of Patent Examining Procedure. MPEP 2144.04IIB; *In re Edge*, 149 USPQ 556 (CCPA 1966). Accordingly, it is submitted that the rejection is deficient for this reason as well.

It is respectfully submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

B. Rejection over Spange in view of Avnir

Claims 13 and 26-32 were rejected under 35 U.S.C. § 103(a) as being obvious over Spange in view of Avnir. (Paper No. 20100806 at 7.)

Spange and Avnir are summarized above.

In making the rejection, the Examiner referred to and incorporated the rejection made under 35 U.S.C. § 102(b) of claims 13 and 26-32 over Spange. (Id.)

The Examiner asserted that “[a]lthough, Spange teaches a method of encapsulating chromophores with an improved sol-gel process, [Spange] fails to teach its product used in a sunscreen composition. However, Avnir et al. teaches a method of entrapping chromophore derivatives in a sol-gel composition wherein the product is utilized as a sunscreen composition (col. 3, lines 15-17). Avnir et al. teaches that due to the carcinogenic nature of chemical sunscreens, it is essential to isolate the chemical sunscreen agents from the body while retaining the sunscreen ability to absorb light (col. 1, lines 65-col. 2, lines 1-5). Avnir et al. teaches that its sol-gel matrices are transparent to the UV radiation and thus allow light to reach the UV absorbing chromophores (col. 3, lines 18-22), while isolating the chromophores from skin, preventing its absorption and thus protecting the skin. Therefore, it would have been obvious to one of ordinary skill in the art to apply a UV absorbing agent as a sunscreen agent as taught by Avnir et al. to the transparent sol-gel matrix of Spange et al. in order to entrap and isolate the sunscreen agent from the body.” (Id. at 7-8.)

As noted above, to forward prosecution in the present application, claim 13 has been amended to recite “[a] sunscreen composition *for topical administration to human skin* comprising microcapsules having UV filter activity ... *and a cosmetic auxiliary agent.*”

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

The responses submitted above in reply to the anticipation rejection over Spange and the obviousness rejection over Avnir alone are incorporated herein.

Spange does not disclose, suggest, or provide motivation for sunscreen compositions of the claimed invention. As the Examiner has acknowledged, "Spange does not refer to its silicate-based xerogel as a sunscreen composition..." (Paper No. 20100806 at 3.) Spange discloses, rather, preparation of xerogels for use in applications such as "nonlinear-optical (NLO) materials, semiconductors, or for use in sensors." (Page 1729, lines 7-8.) Accordingly, one skilled in the art would understand that Spange neither formulates the disclosed xerogels "for topical administration to human skin" nor with "a cosmetic auxiliary agent."

Furthermore, the xerogel produced according to the one-pot synthesis of Spange is not suitable for formulation in a cosmetic formulation, i.e., for topical administration to human skin. Spange discloses that the sol gel hybrid materials are synthesized in tetraethoxysilane ("TEOS") as the solvent. (Page 1729, left column, line 22-26 and right column, lines 1-3.) Material Safety Data Sheets which are attached as Exhibit A indicate that TEOS is a hazardous substance. One skilled in the art would know that the xerogel compositions of Spange cannot be used as cosmetic sunscreen compositions because TEOS is toxic. As is known to the skilled person it is necessary

that a sunscreen composition for topical use have acceptable skin tolerance and be able to spread well onto the skin. In particular, in sunscreen compositions only skin-tolerable and nontoxic substances are permissible. These characteristics of cosmetic formulations are not met by Spange in view of the disclosed industrial uses such as "non-linear optical (NLO) materials, semiconductors, or for use in sensors". (Col. 1, lines 7-8.) The industrial compositions of Spange are far from the cosmetic compositions of the present invention such as, e.g., claim 13 directed to "sunscreen compositions" for topical administration to human skin.

Furthermore, Spange touts the benefits of using the toxic substance, TEOS. (Page 1729, lines 1-3 and paragraph bridging pages 1729-1730.) This is in contravention to the claimed invention for topical administration to human skin.

Moreover, one skilled in the art would find no reason to look to Spange which relates to the noted uses in semiconductor and other industrial applications with regard to formulation of a topical sunscreen composition; nor would Spange be considered in combination with Avnir.

As noted above, Avnir discloses that the sol-gel matrix is transparent to the UV range above 250 nm. The transparency permits UV-A and UV-B light to penetrate the sol-gel particles and interact with the entrapped sunscreen molecules. According to Avnir it is essential that non-crosslinked chromophores are present in the sol-gel matrix, and Avnir particularly touts the advantage of entrapping the chromophores without crosslinking, as (only) this way no reaction with the sunscreen molecule itself is needed. (Col. 4, lines 23-33). One skilled in the art reading Avnir would recognize that Avnir's sunscreen could only provide sufficient UV protection when



non-crosslinked chromophores are entrapped in the transparent sol-gel matrix. Avnir considers the free monomeric sunscreen molecules to be essential in order to obtain suitable sunscreen protection.

With regard to the claimed invention, however, it has been found that contrary to the disclosure of Avnir it is not necessary to dope particles of a sol-gel matrix with monomeric sunscreen molecules.

One skilled in the art would not reasonably expect, in view of Avnir, that microcapsules prepared by the sol-gel method which are free of monomeric sunscreen molecules, would provide a sufficiently high SPF value to be useful in cosmetic sunscreen agents. No examples of sunscreen compositions as presently claimed are disclosed in Avnir, and no process for preparing a sol-gel matrix according to the present application is provided. Avnir does not suggest or consider that a sunscreen moiety covalently bonded to the matrix of the sol-gel particles in the absence of non-crosslinkable chromophores with UV-A and/or UV-B and/or UV-C filter activity would be sufficient to provide a reasonable sun-protecting factor in a cosmetic composition. Far from suggesting the present invention, Avnir leads one skilled in the art away from the claimed invention because Avnir considers it as essential that the sol-gel matrix have entrapped sunscreen molecules to provide a sufficient sun-protecting factor for use in cosmetic compositions.

Avnir recognizes that that chemical sunscreens may be carcinogenic (Col. 1, line 66 to Col. 2, line 1) and the "great need for isolating chemical ... sunscreen agents from the body while retaining ... the sunscreen activity...." (Col. 1, line 65 to col. 2, line 5). In connection with Avnir's disclosed sunscreen-doped sol-gel materials, Avnir

discloses that “[t]he entrapped sunscreen molecules are not in direct contact with the skin.” (Col. 4, lines 53-55.) Yet Avnir does not disclose, suggest, or provide motivation to solve the problem of monomeric sunscreen agents coming into contact with the skin and to provide an effective sunscreen in any way other than Avnir’s transparent sol gel material doped with monomeric sunscreen agents.

As noted above, the Examiner has mischaracterized the use of non-crosslinkable chromophores of Avnir as “extra”. The Examiner stated that “it is the examiner's position that one of ordinary skill in the art would find [sic] it obvious not to include the extra sunscreens component to the sol-gel composition as long as a satisfactory sunscreens effect is achieved with the crosslinkable chromophores alone.” (Paper No. 20100806 at 6.) The disclosure of Avnir indicates that non-crosslinkable chromophores are essential, as indicated above, rather than “extra,” as improperly characterized by the Examiner.

Furthermore, Avnir contains no suggestion or motivation to achieve the claimed sunscreen composition having crosslinkable chromophores as recited and which is “free from non-crosslinkable chromophores with UV-A and/or UV-B and/or UV/C filter activity.” Nor does Avnir contain any indication or suggestion that use of “crosslinkable chromophores alone,” as referred to by the Examiner, could possibly achieve “a satisfactory sunscreens effect”; nor does Avnir suggest how one would go about achieving such hypothetical effect.

As noted above, the claimed invention may be characterized as omission of an element with retention of the element’s function. The aspect of an omission, i.e., recited lack in the claim language of non-crosslinkable chromophores in the claimed

sunscreen composition, yet retention of function, i.e., sunscreen activity in the presence of a crosslinkable chromophore as recited in claim 13, are indicia of ***unobviousness***, according to the Manual of Patent Examining Procedure. MPEP 2144.04IIB; *In re Edge*, 149 USPQ 556 (CCPA 1966). Accordingly, it is submitted that for this reason also the rejection must fail.

As noted above, one skilled in the art would not have considered the disclosure of Spange in relation to the claimed invention. And, one skilled in the art would not have considered Spange and Avnir in combination. Even if a skilled person had considered the disclosure of Spange as well as Avnir in combination, he would, in view of Avnir, not have assumed that the chromophoric silicate based xerogels can be used in cosmetic compositions to solve the problem as addressed in the present application. Rather, from Avnir it follows that one skilled in the art would have considered the xerogels as disclosed in Spange, which contain chromophores covalently bonded to the polymer network, as not being sufficient to provide adequate sun protection to the skin.

Furthermore, one skilled in the art simply would not have been motivated to combine Spange with Avnir. For example, the sol-gel material of Spange includes TEOS, a toxic substance. TEOS is touted by Spange as advantageous in the disclosed reaction. One skilled in the art would have no reason to consider Spange in combination with Avnir because Spange's sol-gel material is incompatible with a sunscreen composition for topical administration to human skin.

Even if one were to combine the disclosures of Spange and Avnir, which can only be done based on impermissible hindsight, the skilled person would not have

arrived at the present invention. This is so because Avnir discloses that it is necessary that the sol gel matrices be doped with monomeric chromophoric molecules in order to provide a suitable sun protection for the skin. Consequently, a skilled person would have provided non-crosslinkable chromophoric molecules as required by Avnir, so that those molecules can be entrapped in the xerogel. Thus, a skilled person, even if he had considered the disclosure of Spange, would not have reached the subject matter of the present application. No reason is discernible to make the substitutions asserted by the Examiner.

Furthermore, to achieve the claimed sunscreen composition which comprises "microcapsules having UV filter activity made by a sol-gel method and which are free from non-crosslinkable chromophores with UV-A and/or UV/B and/or UV/C filter activity," the Spange and Avnir compositions would have to be altered in a manner not intended and, in fact, contrary to their teachings. As noted above, to do what the prior art teaches against is the very antithesis of obviousness. See, *e.g.*, *In re Rosenberger*, 156 USPQ at 26; and *In re Buehler*, 185 USPQ at 787.

As indicated previously on the record, the Court of Appeals for the Federal Circuit has reaffirmed that "hindsight claims of obviousness" are improper. In distinguishing between fact patterns where a combination of known elements may or may not be proper, the Federal Circuit clearly articulated that simply varying all possible parameters until the claimed invention is arrived at in the absence of either an indication of which parameters to vary or an indication of which of many possible choices is likely to be successful is impermissible hindsight reconstruction. Indeed, the Federal Circuit concluded:

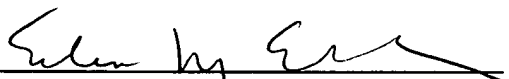
Similarly, patents are not barred just because it was obvious "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 90 USPQ2d 1947, 1951 (Fed. Cir. 2009), citing *In re O'Farrell*, 853 F.2d at 903.

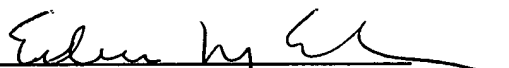
Clearly, the rejection is based on impermissible hindsight reconstruction and is improper. In view of all of the foregoing, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

For the reasons set forth above, entry of the amendments, withdrawal of the rejections and allowance of the claims are respectfully requested. Issuance of a Notice of Allowance is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

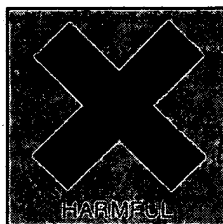
Respectfully submitted,

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 17, 2010.

  
Eileen M. Ebel Reg. No. 37,316

By:   
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# Safety data for tetraethyl orthosilicate



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Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

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## General

Synonyms: ethyl silicate, tetraethoxysilane, silicic acid tetraethyl ester, TEOS, tetraethyl silicate

Molecular formula:  $(C_2H_5O)_4Si$

CAS No: 78-10-4

EINECS No: 201-083-8

Annex I Index No: 014-005-00-0

## Physical data

Appearance: colourless liquid with an alcohol-like odour

Melting point: -86 C

Boiling point: 169 C

Vapour density: 7.2 (air = 1)

Vapour pressure: 2 mm Hg at 20 C

Density ( $g\ cm^{-3}$ ): 0.94

Flash point: 39 C (closed cup)

Explosion limits:

Autoignition temperature:

Water solubility:

## Stability

Stable. Flammable. Incompatible with strong oxidizing agents, water, alkalies, mineral acids.

## Toxicology

Harmful if inhaled. Skin and eye irritant. Long-term exposure may cause kidney or liver damage. Typical TLV/TWA 10 ppm. Typical STEL 30 ppm.

### Toxicity data

(The meaning of any toxicological abbreviations which appear in this section is given [here](#).)

ORL-RAT LD50 6270 mg kg<sup>-1</sup>

### Risk phrases

(The meaning of any risk phrases which appear in this section is given [here](#).)

R10 R20 R36 R37.

## Transport information

(The meaning of any UN hazard codes which appear in this section is given [here](#).)

UN No 1292. Hazard class 3. Packing group III.

## Personal protection

Safety glasses, adequate ventilation. Vapour is much heavier than air, and precautions should be taken to prevent the vapour flowing to a source of ignition.

### Safety phrases

(The meaning of any safety phrases which appear in this section is given [here](#).)

S24 S25.

[Return to [Physical & Theoretical Chemistry Lab. Safety home page](#).]

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This information was last updated on July 11, 2007. We have tried to make it as accurate and useful as possible, but can take no responsibility for its use, misuse, or accuracy. We have not verified this information, and cannot guarantee that it is up-to-date.

Note also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "http://msds.chem.ox.ac.uk/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

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## MATERIAL SAFETY DATA SHEET

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### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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**MATHESON TRI-GAS, INC.**  
**150 Allen Road Suite 302**  
**Basking Ridge, New Jersey 07920**  
**Information: 1-800-416-2505**

**Emergency Contact:**  
**CHEMTREC 1-800-424-9300**  
**Calls Originating Outside the US:**  
**703-527-3887 (Collect Calls Accepted)**

### SUBSTANCE: TETRAETHYLORTHOSILICATE

#### TRADE NAMES/SYNONYMS:

ETHYL SILICATE ((ETO)<sub>4</sub>Si); ETHYL SILICATE; SILICIC ACID (H<sub>4</sub>SiO<sub>4</sub>), TETRAETHYL ESTER;  
ETHYL ORTHOSILICATE; SILICON ETHOXIDE; SILICON ETHOXIDE (Si(OET)<sub>4</sub>); SILICON  
TETRAETHOXIDE; SILICON TETRAETHOXIDE (Si(OET)<sub>4</sub>); TETRAETHOXYSILANE;  
TETRAETHOXYSILICON; TETRAETHYL ORTHOSILICATE; TETRAETHYLOXYSILANE;  
TETRAETHYL SILICATE; DYNASIL A; TEOS; C<sub>8</sub>H<sub>20</sub>O<sub>4</sub>Si; UN 1292; STCC 4910391; MAT09230;  
RTECS VV9450000

**CHEMICAL FAMILY:** esters, carboxylic, aliphatic, silicon

**CREATION DATE:** Nov 11 1997

**REVISION DATE:** Dec 11 2008

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### 2. COMPOSITION, INFORMATION ON INGREDIENTS

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**COMPONENT:** TETRAETHYLORTHOSILICATE

**CAS NUMBER:** 78-10-4

**PERCENTAGE:** 100.0

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### 3. HAZARDS IDENTIFICATION

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**NFPA RATINGS (SCALE 0-4):** HEALTH=2 FIRE=3 REACTIVITY=1

#### EMERGENCY OVERVIEW:

**COLOR:** colorless

**PHYSICAL FORM:** liquid

**ODOR:** alcohol odor

**MAJOR HEALTH HAZARDS:** respiratory tract irritation, skin irritation, eye irritation, central nervous system depression

**PHYSICAL HAZARDS:** Flammable liquid and vapor. Vapor may cause flash fire. May react on contact







with water.

**POTENTIAL HEALTH EFFECTS:**

**INHALATION:**

**SHORT TERM EXPOSURE:** irritation, nausea, vomiting, headache, symptoms of drunkenness, lung congestion

**LONG TERM EXPOSURE:** lung damage, kidney damage, liver damage

**SKIN CONTACT:**

**SHORT TERM EXPOSURE:** irritation

**LONG TERM EXPOSURE:** same as effects reported in short term exposure

**EYE CONTACT:**

**SHORT TERM EXPOSURE:** irritation, burns, tearing, blurred vision

**LONG TERM EXPOSURE:** same as effects reported in short term exposure

**INGESTION:**

**SHORT TERM EXPOSURE:** nausea, vomiting, diarrhea, headache

**LONG TERM EXPOSURE:** same as effects reported in short term exposure

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**4. FIRST AID MEASURES**

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**INHALATION:** If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

**SKIN CONTACT:** Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

**EYE CONTACT:** Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

**INGESTION:** If a large amount is swallowed, get medical attention.

**NOTE TO PHYSICIAN:** For ingestion, consider gastric lavage and activated charcoal slurry.

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**5. FIRE FIGHTING MEASURES**

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**FIRE AND EXPLOSION HAZARDS:** Severe fire hazard. The vapor is heavier than air. Vapors or gases may ignite at distant ignition sources and flash back. Vapor/air mixtures are explosive above flash point.

**EXTINGUISHING MEDIA:** regular dry chemical, carbon dioxide, water, regular foam

Large fires: Use regular foam or flood with fine water spray.

**FIRE FIGHTING:** Move container from fire area if it can be done without risk. Do not get water inside container. Cool containers with water spray until well after the fire is out. Stay away from the ends of tanks.



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Withdraw immediately in case of rising sound from venting safety device or any discoloration of tanks due to fire. For tank, rail car or tank truck, evacuation radius: 800 meters (1/2 mile). Do not attempt to extinguish fire unless flow of material can be stopped first. Cool containers with water spray until well after the fire is out. Apply water from a protected location or from a safe distance. Do not get water directly on material. Large fires: Flood with fine water spray. Reduce vapors with water spray. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

**FLASH POINT:** 99 F (37 C) (CC)

**LOWER FLAMMABLE LIMIT:** 1.3%

**UPPER FLAMMABLE LIMIT:** 23%

**FLAMMABILITY CLASS (OSHA):** IC

**HAZARDOUS COMBUSTION PRODUCTS:**

Thermal decomposition or combustion products: oxides of carbon, silica

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## 6. ACCIDENTAL RELEASE MEASURES

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**OCCUPATIONAL RELEASE:**

Avoid heat, flames, sparks and other sources of ignition. Do not touch spilled material. Stop leak if possible without personal risk. Reduce vapors with water spray. Do not get water inside container. Small spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal. Large spills: Dike for later disposal. Remove sources of ignition. Keep unnecessary people away, isolate hazard area and deny entry.

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## 7. HANDLING AND STORAGE

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**STORAGE:** Store and handle in accordance with all current regulations and standards. Store in a cool, dry place. Store in a tightly closed container. Store under an inert atmosphere. Subject to storage regulations: U.S. OSHA 29 CFR 1910.106. Grounding and bonding required. Keep separated from incompatible substances.

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## 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

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**EXPOSURE LIMITS:**

**TETRAETHYLORTHOSILICATE:**

**ETHYL SILICATE:**

100 ppm (850 mg/m<sup>3</sup>) OSHA TWA

10 ppm (85 mg/m<sup>3</sup>) OSHA TWA (vacated by 58 FR 35338, June 30, 1993)

10 ppm ACGIH TWA

10 ppm (85 mg/m<sup>3</sup>) NIOSH recommended TWA 10 hour(s)

**ETHYL ALCOHOL (ETHANOL):**

1000 ppm (1900 mg/m<sup>3</sup>) OSHA TWA

1000 ppm ACGIH TWA



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1000 ppm (1900 mg/m<sup>3</sup>) NIOSH recommended TWA 10 hour(s)

**VENTILATION:** Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

**EYE PROTECTION:** Wear splash resistant safety goggles with a faceshield. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

**CLOTHING:** Wear appropriate chemical resistant clothing.

**GLOVES:** Wear appropriate chemical resistant gloves.

**PROTECTIVE MATERIAL TYPES:** neoprene, Viton(R)

**RESPIRATOR:** The following respirators and maximum use concentrations are drawn from NIOSH and/or OSHA.

**100 ppm**

Any supplied-air respirator.

**250 ppm**

Any supplied-air respirator operated in a continuous-flow mode.

**500 ppm**

Any self-contained breathing apparatus with a full facepiece.

Any supplied-air respirator with a full facepiece.

**700 ppm**

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.

Emergency or planned entry into unknown concentrations or IDLH conditions -

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

**Escape -**

Any air-purifying full-facepiece respirator (gas mask) with a chin-style, front-mounted or back-mounted organic vapor canister.

Any appropriate escape-type, self-contained breathing apparatus.

Under conditions of frequent use or heavy exposure, respiratory protection may be needed.

Respiratory protection is ranked in order from minimum to maximum.

Consider warning properties before use.

Any chemical cartridge respirator with organic vapor cartridge(s).

Any chemical cartridge respirator with a full facepiece and organic vapor cartridge(s).

Any air-purifying respirator with a full facepiece and an organic vapor canister.

**For Unknown Concentrations or Immediately Dangerous to Life or Health -**

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.



Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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**PHYSICAL STATE:** liquid

**COLOR:** colorless

**ODOR:** alcohol odor

**MOLECULAR WEIGHT:** 208.33

**MOLECULAR FORMULA:** (C<sub>2</sub>H<sub>5</sub>)<sub>4</sub>SiO<sub>4</sub>

**BOILING POINT:** 329-336 F (165-169 C)

**FREEZING POINT:** -123 to -107 F (-86 to -77 C)

**VAPOR PRESSURE:** 2 mmHg @ 20 C

**VAPOR DENSITY (air=1):** 7.2

**SPECIFIC GRAVITY (water=1):** 0.920-0.950

**WATER SOLUBILITY:** decomposes

**PH:** Not available

**VOLATILITY:** 99.9%

**ODOR THRESHOLD:** 85 ppm

**EVAPORATION RATE:** 0.3 (butyl acetate=1)

**VISCOSITY:** 0.0179 cP @ 20 C

**COEFFICIENT OF WATER/OIL DISTRIBUTION:** Not available

**SOLVENT SOLUBILITY:**

**Soluble:** alcohol, ether

**Slightly Soluble:** benzene

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## 10. STABILITY AND REACTIVITY

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**REACTIVITY:** Contact with water or moist air may form flammable and/or toxic gases or vapors.

**CONDITIONS TO AVOID:** Avoid heat, flames, sparks and other sources of ignition. Minimize contact with material. Keep out of water supplies and sewers.

**INCOMPATIBILITIES:** acids, bases, oxidizing materials, combustible materials

**HAZARDOUS DECOMPOSITION:**

Thermal decomposition or combustion products: oxides of carbon, silica

Thermal decomposition products: alcohols, silicon

**POLYMERIZATION:** Will not polymerize.

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## 11. TOXICOLOGICAL INFORMATION

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**TETRAETHYLORTHOSILICATE:**

**IRRITATION DATA:** 3000 ppm eyes-human; 500 mg/24 hour(s) skin-rabbit moderate; 100 mg eyes-rabbit mild; 500 mg/24 hour(s) eyes-rabbit mild; 2500 ppm/2 hour(s) eyes-guinea pig severe

**TOXICITY DATA:** 30 gm/m3 inhalation-mouse LC50; 6300 ul/kg skin-rabbit LD50; 6270 mg/kg oral-rat LD50

**LOCAL EFFECTS:**

Irritant: inhalation, skin, eye

**ACUTE TOXICITY LEVEL:**

Moderately Toxic: inhalation

Slightly Toxic: dermal absorption, ingestion

**TARGET ORGANS:** central nervous system

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** blood system disorders, eye disorders, kidney disorders, liver disorders, respiratory disorders, skin disorders and allergies

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**12. ECOLOGICAL INFORMATION**

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**ECOTOXICITY DATA:**

**INVERTEBRATE TOXICITY:** 4000 ug/L 15 month(s) LETH (Mortality) Water flea (Daphnia magna)

**ALGAL TOXICITY:** 1000 ug/L 30 month(s) LETH (Mortality) Green algae (Chlorella vulgaris)

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**13. DISPOSAL CONSIDERATIONS**

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Dispose in accordance with all applicable regulations. Subject to disposal regulations: U.S. EPA 40 CFR 262. Hazardous Waste Number(s): D001. Dispose in accordance with all applicable regulations.

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**14. TRANSPORT INFORMATION**

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**U.S. DOT 49 CFR 172.101:**

**PROPER SHIPPING NAME:** Tetraethyl silicate

**ID NUMBER:** UN1292

**HAZARD CLASS OR DIVISION:** 3

**PACKING GROUP:** III

**LABELING REQUIREMENTS:** 3



**CANADIAN TRANSPORTATION OF DANGEROUS GOODS:**

**SHIPPING NAME:** Tetraethyl silicate

**UN NUMBER:** UN1292

**CLASS:** 3

**PACKING GROUP/CATEGORY:** III



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## 15. REGULATORY INFORMATION

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### U.S. REGULATIONS:

**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.

**SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355 Subpart B):** Not regulated.

**SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355 Subpart C):** Not regulated.

**SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370 Subparts B and C):**

ACUTE: Yes

CHRONIC: No

FIRE: Yes

REACTIVE: Yes

SUDDEN RELEASE: No

**SARA TITLE III SECTION 313 (40 CFR 372.65):** Not regulated.

**OSHA PROCESS SAFETY (29 CFR 1910.119):** Not regulated.

### STATE REGULATIONS:

**California Proposition 65:** Not regulated.

### CANADIAN REGULATIONS:

**WHMIS CLASSIFICATION:** Not determined.

### NATIONAL INVENTORY STATUS:

**U.S. INVENTORY (TSCA):** Listed on inventory.

**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

**CANADA INVENTORY (DSL/NDL):** Not determined.

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## 16. OTHER INFORMATION

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